

I. Basis of Report

1. Regarding the **components** of the international application (*replacement pages filed with the Application Office in response to a request under Article 14 are deemed "originally filed" in the context of this report and are not attached because they contain no amendments (Rules 70.16 and 70.17))*):

Specification, pages:

1-11 in the version originally filed

Claims, Nos.:

1-23 received on 9/2/04 with letter of 9/2/04

V. Finding with supporting reasons according to Article 35(2) regarding novelty, inventive step, and industrial applicability; documents and explanations in support of this finding.

1. Finding

Novelty Yes: Claims 1-23
 No: Claims

Inventive step: Yes: Claims
 No: Claims 1-23

Industrial applicability: Yes: Claims 1-23
 No: Claims

2. Documents and explanations
see attachment

- D1: PETER C ET AL: 'OPTICAL DNA SENSOR CHIP FOR REAL-TIME DETECTION OF HYBRIDIZATION EVENTS' FRESNIUS JOURNAL OF ANALYTICAL CHEMISTRY, SPRINGER, BERLIN, DE, Vol. 371, No. 2, September 2001 (2001-09), Pages 120-127, XP009016890 ISSN: 0937-0633
- D2: US-B1 6 197 503 (VO-DINH TUAN ET AL) March 6, 2001 (2001-03-06)
- D3: WO 00 68692 A (DANIELS R HUGH; WONG EDITH Y (US); BRUCHEZ MARCEL P (US); EMPEDOCL) November 16, 2000 (2000-11-16)

Novelty and Inventive Step

- 1.1 D1 describes an optical DNA sensor chip for detecting hybridizing DNA. DNA targets are tagged with fluorophors (corresponding to ligands). These targets bind to immobilized DNA probes (corresponding to receptors), (page 120, left column, abstract). "Molecular beacons" are used as DNA probes to increase sensitivity (page 121, left column, paragraph 2). As defined in the present Application (page 4, lines 11-37), these "beacons" have a fluorochrome. The DNA probes are also biotinylated (page 122, right column, paragraph 3 and page 121, table). Detection of targets tagged with fluorophors is possible using the optical sensor system in D1. By using "beacons" that also contain a fluorophor, the separate detection of receptor-marker molecules ("molecular beacon" as DNA probe in D1) likewise appears to be possible.
- 1.2 D2 describes a DNA biosensor for detecting nucleic acids. This biosensor consists of a "biochip" that contains multiple biological sensor elements, namely DNA probes (receptor-marker complex). The DNA probes are immobilized on a detector surface (column 7, paragraph 2). It is apparent from Example 15 that the gene "probes" are tagged with fluorescein. It is thus possible in D2 also to detect the receptor-marker complexes independently of the receptor-ligand complexes.
- 1.3 D3 (WO-A-0 068 692) describes how both the immobilized antigens and the antibodies

are spectrally detectable (Fig. 1 C). Receptor-marker complexes can therefore be determined independently of the receptor-ligand complexes in D3.

Differently from these documents, Claim 1 of the present Application is limited to methods for determining receptors on a carrier. The receptors here are detectable only after immobilization on the carrier, because **receptor-marker complexes** are formed only after immobilization.

2. These documents are all viewed independently of one another as current state of the art. Based on these documents, the goal of this Application can be defined as an improved method for determining the number of receptors on a carrier surface, by which the amount of actually immobilized receptors can be determined exactly. The solution as represented in Claims 1-23 is methods by which receptor-marker complexes are detected independently of receptor-ligand complexes.
This method actually does not derive from the cited documents, but there is no evidence for this actual effect in the Application. No tests at all are presented that indicate this effect. If the invention rests on a technical effect, it must be possible to produce this over the entire breadth of the claims. This is not shown, and therefore no inventive step can be recognized.
Claims 1-23 can thus not be allowed under PCT Art. 33(3).
3. In addition, it is also pointed out that Claim 23 is worded in the form of a "product by process" claim. The PCT treaty states do not have uniform criteria for this type of claim. For the EPA, this type of claim in which products are characterized by the production process is allowable only when the product as such meets the criteria for patentability, or in other words the products as such are novel and inventive.